Licensing Guide for Veterinary Licenses

This guide is intended to assist applicants in the development of a radiation safety program for use of radiopharmaceuticals in animals. The applicant must submit complete, accurate and detailed information for each of the items listed below. RHB form 2050 is the application used for veterinary licensing. Copies of this guide are available on the internet at www.dhs.ca.gov/rhb.

Item 1: a) Name of Applicant:

Specify the name of the company or business entity responsible for the radiation safety program.

b) Mailing address: California only

c) Phone number: California only

Item 2 a) Type of business: Sole proprietorship, group, corporation, university. Provide copy of Articles of Incorporation.

b) Location of use:List all Radioactive Material (RAM) locations of use and include room numbers if applicable.

Generally each RAM license may have only one RAM use location. Exceptions will be evaluated by RHB staff.

Location(s) of use must have a letter from the landlord/building owner allowing use of RAM and unrestricted entry into facility to retrieve all RAM and decontaminate facility in case of disharmony between the parties.

c) Application type: Self-Explanatory

Item 3: a) Nuclide(s): Specify isotopes to be used

b) Form: Any for unsealed material and sealed sources with model numbers if applicable for sealed sources..

c) Possession limit: State maximum possession limit to meet demand. The possession limit includes the material in storage and animal excreta.

Item 4: a) Proposed use: Select the proposed use(s) as follows:

1. diagnostic imaging in animals
2. hyperthyroidism and/or thyroid tumors in animals
3. Palliative treatment in animals
4. Marker and calibration sources for calibration of instruments
5. Brachytherapy
6. Other:_____(describe)

Item 5: Radiation Safety Officer and authorized user training requirements:

A. Submit a Duties and Responsibilities of the Radiation Safety Officer (RSO) and Delegation of Authority form. Form must be signed by the RSO designee and a senior member of management such as the CEO, COO, Vice-President, President or Owner.

B. Submit a completed Training and Experience (T&E) form RH-2050A for the RSO and supervisory users. Supervisory users shall only be the Veterinarian. As the supervisory user, the Veterinarian must be intimately involved in the radiation safety program. Describe how the DVM will remain involved including number of hours per week the DVM is actually on site. Animals having undergone Iodine therapy may only be released to the owner by the DVM. The T&E requirements are as follows:

1. The veterinarian shall be a board certified Radiologist prior to 1994 or Board Certified Radiation Oncologist after 1994 or;

2. The veterinarian shall have completed training and experience for the total required hours:

a. For diagnostic procedure:
(1) 40 hours of didactic training and
(2) 40 hours of clinical training whose preceptor is qualified as in B.1. above. This clinical training must be pre-approved by the department.

b. For therapeutic procedures with isotopes:
(1) 40 hours of didactic training and
(2) 80 hours of clinical training whose preceptor is qualified as in B.1. above. This clinical training must be pre-approved by the department.

C. Submit a training program, including annual refresher training program, provided to individuals who will act as the radiation workers supervised by the supervisory users listed in B. above. Provide an outline of the topics covered in their didactic training and describe their on-the-job training process. Commit to maintaining records of each radiation worker's training log and training completion certificate.

Item 6 Radiation Detection Instruments:

Complete the table shown on form RH-2050. Survey instrumentation must include exposure rate instrumentation and wipe test instrumentation. Your wipe test instrumentation must be sensitive enough to detect the contamination action levels you use. Submit evidence that the Minimum Detectable Activity (MDA) of the instrument meets your action levels.

$$2.71 + 4.65 \text{ SQRT } (B)$$

$$MDA = \frac{}{Eff}$$

Where: B Background (cpm)
Eff detector efficiency

Contamination action levels: 2000 dpm/100 cm2 (isotopes other than iodine)
200 dpm/100 cm2 (iodine)
Suggested exposure action levels: 2.0 mR/hr (restricted areas)
0.05 mR/hr (unrestricted)

Item 7 Method, frequency and standards used in calibrating instruments listed in item 6.

A. Provide the name of the authorized service company who will be calibrating survey meters. You may commit to utilizing any other authorized service company in the future to avoid amendments involving such a change.

B. If calibrated by the Licensee submit procedures including:

(1) Calibration standard (energy, activity, accuracy)
(2) Two point on each scale
(3) ± 10 percent

C. The frequency shall be at least annually and following repair.

D. Specify sources used for calibration of the liquid scintillation, NaI or gamma well counter. Indicate if these are received as exempt or should be included under Item 3 of the application.

Item 8 Personnel monitoring and bioassay procedures.

Submit a description of personnel monitoring and frequency of exchange including:

A. Whole body film badge or Thermoluminescence Dosimeter (TLD).

B. Extremity film badge or TLD.

C. NVLAP approved vendor.

(1) Note: If using radiopharmaceutical human use grade Iodine-131 for therapy procedures then bioassays are not required.

Item 9: Facilities and Equipment

Provide a labeled facility diagram showing RAM use and storage locations in relation to the rest of the facility. Specify restricted versus unrestricted areas and describe shielding. Also include the following:

A. Security identified/described
B. Remote handling equipment
C. Hot lab diagram
D. Waste areas identified including decay-in-storage
E. Generator storage areas identified, if applicable
F. Isotope storage areas identified
G. Commitment to post areas where RAM is used or stored
H. RAM use injection areas identified.
I. Animal holding areas identified

Item 10 Radiation Safety Program

Note: Please refer to NRC attachments (Appendix H, Considerations for Laboratory Animal and Veterinary Medicine Uses and Item 8.11, waste management) for additional information on Veterinary Radiation Safety Programs.

A. Commit to conspicuous posting of form RH-2364 (Notice to Employees) which is supplied by the Department with the license. Also commit to posting the license, operating procedures, and regulations or if not practical, where these items may be found.

B. Provide the "General Safety Rules" which will be followed by all users of RAM. Commit to providing initial and annual refresher training on these topics to keep the users informed (Section 30255 of Title 17). Commit to maintaining records for inspection. Include the following descriptions:

<u>General Rules for the Safe Use of Radioactive Material</u>

1) Instructions
2) Lab Coats
3) Gloves
4) Logbook and labels for doses
5) Monitoring hands
6) Syringe shields
7) No eating, drinking, smoking or storage in RAM use areas
8) Procedures on moving and/or transporting RAM
9) Personnel monitoring instructions
10) Description of contamination control and personnel monitoring surveys, after each procedure and at the end of the day.

<u>Personnel Training Program:</u>

1) Training frequency
2) Before using RAM
3) Before working in vicinity
4) Annual refresher
5) Training Procedures Submitted for staff and ancillary personnel
6) Topics:

a) Licensees ALARA program
b) Annual dose limits
c) Identification of use locations
c) Potential Hazards
d) Safety precautions appropriate to duties (minimize exposure)
e) Pregnancy policy
f) Regulations
g) Duty to report unsafe conditions
h) Location of notices, copies of regulation and license
i) Properly documented

C. Submit ordering, receipt, inventory control and sealed source leak test procedures. These procedures should be performed in accordance with 10CFR20 Section 1906.

Procedures for Ordering and Receiving:

1) Procedures for ordering and receiving
2) Procedures for whom can order materials
3) Procedures during working hours
4) Storage location for off-duty hours
   a) Off-duty hour RAM receipt procedures

Radioactive Materials Package Opening Procedures:

1) Procedure for opening packages
2) Radiation level monitoring (10 mR/hr at one meter, 200 mR/hr at surface)
3) Wipes taken on the outer container (2,200 dpm/100 cm^2 limit)
4) Check packing material for contamination
5) Report excessive levels to RSO

Records of Possession and use of RAM

1) Procedure for maintaining records of RAM
2) Records of Unit dosage used
3) Records of Multi-Dose vial use

Sealed Source Leak Test

1) Vendor doing leak test
2) Licensee doing leak test:
   a. Frequency (every 6 months)
   b. Minimum detectable activity (0.005 uCi or better)
   c. Instrumentation
   d. Specify procedures

D. Provide area survey procedures. In general, daily surveys of work areas should be done (no record unless a positive result is found), and weekly recorded surveys will be maintained for inspection. The following should be included:

1) Survey frequencies
2) Daily - Elution, Preparation and injection areas
3) Weekly - All other use areas
4) Ion chamber or energy compensated probe required for surveys
5) NaI detector or gamma well counter required for wipes
6) Records (appropriate units)(dpm/100cm^2 and mR/hr)
7) Exposure trigger levels identified
8) Contamination action levels identified
9) A keyed diagram of wipe/survey test locations

E. Provide Emergency procedures including:

1) Emergency instructions
2) Immediate actions listed (e.g. turn off ventilation, evacuation and containment)
3) Notification of RSO
4) Names and telephone numbers of responsible parties listed and posted
5) Clean-Up Procedures (instructions for reentry, decontamination and recovery)

F. Assure that containers, storage areas, rooms, stalls, pens, and equipment in which radioactive material are used are properly labeled in accordance with 10 CFR 20, sections 1801, 1802 and 1901.

G. Submit a description of your animal release criteria and procedures. Members of the general public may not receive more than 100 mR/year. Your procedures must demonstrate how occupants of the residence or other members of the general public will not be exposed to greater than this exposure limit. **The Department recommends the animals be held for a minimum of 5 - 24 hour periods and not be released until the dose rate is 0.5 mrem / hr at 1 meter for I-131.** Should the licensee choose release guidance different than that described above justification and supporting data must be submitted.

1) Submit a sample of the animal owner instructions with signature/print name and date blocks for both the owner and the authorized user DVM. Date and times of injection and release must be included.
2) Animal excreta is not exempt for disposal. Your procedures must include discussion of how you will deal with the animal excreta.

Item 11 Effluent and environmental monitoring

This item is generally not applicable except for sewer disposal of RAM which is covered in item 12

Item 12 Waste disposal

A. If using the sanitary sewer system, provide estimated monthly water usage by the facility and calculate expected concentrations for each proposed isotope. Compare these with Appendix B of 10 CFR 20.

B. Describe procedures and equipment for containment of animal excreta. Specify how stall, cages, floors and facility ground will be decontaminated.

C. For solid waste packaging, consult with a qualified radioactive waste broker for detailed information.

D. To store for Decay in Storage (DIS)(isotopes with physical half lives less than 65 days), hold for 10 half-lives, survey with pancake probe prior to disposal to verify levels indistinguishable from background, and label removal or defacement. Retain records of surveys and items disposed of for inspection.

E. Also include the following if applicable:

1) Waste will be handled by:
   a) Commercial wasted broker contracted
   b) Transfer to manufacturer or disposal facility
   c) Decayed in Storage on premises
      1) DIS facility diagram
      2) DIS security

Item 13: Decommissioning and Decontamination Plans:

Commit to a thirty day prior notification of your intent to vacate and subsequent submittal of a clearance survey to the Department. You may contact the Radiologic Health Branch for clearance survey requirements.

Item 14: The application must be signed by an official who is legally and financially liable for the corporation.

Attachments:

1. Duties and Responsibilities of the Radiation Safety Officer and Delegation of Authority for Veterinary Facilities

2. U.S. Nuclear Regulatory Commission , NUREG-1556, Volume 7 "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope (Final Report)

Appendix H : Considerations for Laboratory Animal and Veterinary Medicine Uses

Section 8.11 Item 11 Waste Management

Duties and Responsibilities of the Radiation Safety Officer and Delegation of Authority for Veterinary Facilities

Veterinary RSO Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with California and DOT regulations and the conditions of the license. These duties and responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped
- Radiation exposures to personnel are ALARA
- Follows 10 CFR Part 20 and investigational levels
- Up-to-date radiation protection procedures in the daily operation of the licensee's radioactive material program are developed, distributed, and implemented
- Possession, use, and storage of licensed material is consistent with the limitations in the license, the regulations, the SSDR Certificate(s), and the manufacturer's recommendations and instructions
- Individuals installing, relocating, maintaining, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material
- Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained
- Licensed material is properly secured
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, or fire
- Audits of the radiation protection program are performed at least annually and documented
- If violations of regulations or license conditions or program weaknesses are identified, effective corrective actions are developed, implemented, and documented
- Licensed material is transported in accordance with all applicable DOT requirements

- Licensed material is disposed of properly
- Appropriate records are maintained
- Up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner
- Provide periodic on-site direct supervision over the implementation of the Radiation Safety Program in technical and administrative issues by physically visiting the site.
- Dose records and surveys are reviewed quarterly
- ALARA practices are being followed
- New users and uses of radioactive material are reviewed prior to first use

In the event of a proposed change in the facility's RSO or license termination, you are aware of and agree to remain the licensee's RSO until RHB amends this license to reflect this request.

Delegation of Authority

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management of situations where staff are not cooperating and not addressing radiation safety issues. In addition, you are free to raise issues with the California Department of Health Services, Radiologic Health Branch at anytime. You will directly manage the radiation safety program and be physically present at this facility (and any other use locations listed in the Radioactive Materials License) whatever time as may be necessary to ensure that the radiation protection activities are performed.

_____/_____/_____
Signature of Management Representative * / Print or Type Name / Title

I accept the above responsibilities,

_____/_____ DATE:_____
Signature of Radiation Safety Officer / Print or Type Name
cc: Affected department heads

*** Examples of Management representative with signature authority are: Owner, Chief Executive Officer, Chief Operating Officer, President or Vice President of the organization.**

The following was copied from U.S. Nuclear Regulatory Commission , NUREG-1556, Volume 7 "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope (Final Report)

Appendix H : Considerations for Laboratory Animal and Veterinary Medicine Uses

Considerations for Laboratory Animal and Veterinary Medicine Uses

This Appendix provides additional information on the use of byproduct materials in laboratory animals, in animals used for research in the environment, and by veterinarians.

Laboratory Animals

Training

Before allowing an individual to care for animals used in studies with or treated with licensed material, the Radiation Safety Officer (RSO), Authorized User (AU), and/or veterinarian must ensure that he or she has sufficient training and experience to maintain doses ALARA, control contamination, handle waste appropriately, etc.
Classroom training may be in the form of lecture, videotape, or self-study and should cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and using instruments
- Mathematics and calculations basic to using and measuring radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training should consist of:

- Observing authorized personnel using survey equipment, using proper contamination control techniques, and proper disposal of radioactive material
- Using survey equipment, proper contamination control techniques, and proper disposal of radioactive material procedures under the supervision of, and in the physical presence of, an individual authorized to handle animals treated with licensed material or otherwise containing licensed material.

Contamination Control and Waste Handling

In order to minimize the spread of contamination, animals used in studies with or treated with licensed material should be housed in cages or stalls separate from other animals. The facilities, stalls, or cages shall be secured to prevent unauthorized access to the animals. Individuals caring for these animals should reduce the chance of personal contamination by wearing gloves, lab coat, and eye protection, as appropriate.
Special care should be observed when cleaning the cage or stall. The cage or stall, the bedding, and waste from the animal may contain radioactive material. Any radioactive material should be properly disposed of as described in Section 8.11, "Waste Management."
Disposal of laboratory animals that contain radioactive material require special procedures. Animal carcasses that contain less than 1.85 kBq/gram (0.05 microcuries/gram) of carbon-14 or hydrogen-3 may be disposed of by the same method as non-radioactive animal carcasses. Animal carcasses that contain byproduct material with a half-life of less than 120 days may be allowed to decay-in-storage in a freezer dedicated for radioactive material. Animal carcasses must be held for a minimum of 10 half-lives of the longest lived isotope. After 10 half-lives, the animal carcasses may be disposed as non-radioactive, if radiation surveys (performed in a low background area and without any interposed shielding) of the carcasses at the end of the holding period indicate that radiation levels are indistinguishable from background (See section 8.11, "Waste Management").

Animals Used for Research in the Environment

Before a researcher releases an animal that has been injected with a radiopharmaceutical or has had radioactive seeds implanted, the researcher will ensure that the dose that members of the public will receive from the animal is within limits of 10 CFR 20.1301. 10 CFR 20.1301 requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Further, the researcher may be required to perform an assessment of the impact the byproduct material will have on the environment (See section "Purpose(s) for Which Licensed Material Will Be Used").

Veterinary Use

Training

NRC believes that to demonstrate adequate training and experience, the veterinarian should have training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation Protection Principles

- Characteristics of Ionizing Radiation
- Units of Radiation Dose and Quantities
- Radiation Detection Instrumentation
- Biological Hazards of Exposure to Radiation (appropriate to the types and forms of byproduct material to be used)
- Hands-on Use of Radioactive Materials.

The length of the training (usually 40 hours) will depend upon the type, form, quantity and proposed use of the licensed material requested, but training shall cover the subjects stated.

Contamination Control and Waste Handling

See above section, "Laboratory Animals."

Release of Animals

Before a veterinarian releases an animal that has been injected with a radiopharmaceutical or has had radioactive seeds implanted, the veterinarian must ensure that the dose that members of the public (including the animal's caretaker) will receive from the animal is within limits of 10 CFR 20.1301. 10 CFR 20.1301 requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Furthermore, licensees should provide instructions to the animal's caretaker to keep doses ALARA.

Instructions to Animal Caretaker Upon Release

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations. The instructions should not, however, interfere with or contradict the best medical judgment of the veterinarian. The instructions should include the name of a knowledgeable person to contact and that person's telephone number, in case the caretaker has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided.

Sample Instructions to Caretakers of Animals Administered Radiopharmaceuticals or Other Unsealed Materials

Radiopharmaceutical instructions, to the caretaker, should include the following topics:

- Maintaining distance from people
- Minimizing time in public places (e.g., walks on public sidewalk, parks, beaches, grooming salon)
- Precautions to reduce the spread of radioactive contamination, including animal excreta (which may need to be held for decay)[(4)].

- The length of time each of the precautions should be in effect.

Example Radiopharmaceutical Instructions

The animal has been treated with radioactive material (isotope) and still possesses a low level of radioactivity. The present level of radioactivity is below the regulatory agency level necessary for isolating the animal from humans. Because some radioactivity will be present for the next few days, it is necessary that the following safety precautions be exercised for the next days:

1. The animal should be kept inside or in his cage/stall following hospital discharge.
2. The animal should not be permitted to have prolonged contact with children under the age of 12 for days following hospital discharge. Close contact should be limited to less than minutes per day.
3. Pregnant women should avoid ANY contact with the animal or its urine and/or feces for at least days after discharge.
4. Family members should not be permitted to sleep with the animal for days after discharge. They also should limit close contact with the animal (being within 1 meter or 3 feet of the animal) for the next day(s) to no more than minutes a day. Preferably, contact with the animal should be kept to a distance of more than 1 meter or 3 feet for this period.
5. Use a plastic litter pan liners and a scoopable litter (for cats).
6. Disposable gloves should be worn whenever changing the litter box for the next days after discharge.
7. Wash hands after contact with the animal or the litter.
8. Call to discuss any other radiation safety concerns.

Sample Instructions to Caretakers of Animals Implanted with Sealed Sources

A small radioactive source has been placed (implanted) inside the animal. The source is actually many small metallic pellets or seeds, which are each about 1/4" to 1/3" long, similar in size and shape to a grain of rice. The following precautions should be taken for days, to minimize exposure to radiation to humans from the source inside the animal:

- Stay at a distance of feet from .
- Maintain separate sleeping arrangements.
- Minimize time with children and pregnant women.
- Do not hold or cuddle pet.
- Avoid public transportation.
- Examine any bandages that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.

If a seed or pellet has fallen out, do the following:

- Do not handle it with fingers. Use something like a spoon or tweezers to place it in a jar or other container that can be closed with a lid.

- Place the container with the seed or pellet in a location away from people. Telephone _____ at _____.

The following was copied from U.S. Nuclear Regulatory Commission , NUREG-1556, Volume 7 "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope (Final Report)

8.11 Item 11: Waste Management

Regulations: 10 CFR 20.1904, 10 CFR 20.2001, 10 CFR 20.2002, 10 CFR 20.2003, 10 CFR 20.2004, 10 CFR 20.2005, 10 CFR 20.2006, 10 CFR 20.2007, 10 CFR 20.2108, 10 CFR 30.51, 10 CFR 61.52.

Criteria: Radioactive waste must be disposed of in accordance with regulatory requirements and license conditions. Appropriate records of waste disposal must be maintained.

Discussion: Radioactive waste is normally generated when conducting licensed activities. Such waste may include used or unused radioactive material, unusable items contaminated with radioactive material, e.g., absorbent paper, gloves, etc. Licensees may not receive radioactive waste from other licensees for processing, storage or disposal, unless specifically authorized to do so by NRC.
All radioactive waste must be stored in appropriate containers until its disposal and the integrity of the waste containers must be assured. Radioactive waste containers must be appropriately labeled. All radioactive waste must be secured against unauthorized access or removal. NRC requires ARDL licensees to manage radioactive waste generated at their facilities by one or more of the following methods:

- Decay-in-storage (DIS)
- Release into sanitary sewerage
- Transfer to an authorized recipient
- Extended interim storage
- Disposal of waste as if it were not radioactive (specific wastes)
- Obtaining prior approval of NRC of any alternate method
- Release in effluents to unrestricted areas, other than into sanitary sewerage
- Incineration.

Licensees may chose any one or more of these methods to dispose of their radioactive waste. It has been NRC's experience that most of the ARDL facilities store or dispose of radioactive waste by a combination of the first four methods, because of the types and amounts of licensed materials used by these facilities. Applicants wanting to dispose of radioactive waste by incineration should refer to Policy and Guidance Directive PG 8-10, "Disposal of Incinerator Ash as Ordinary Waste," dated January 1997. Applicants should note that compliance with NRC regulations does not relieve them of their responsibility to comply with any other applicable Federal, state, or local regulations. Furthermore, some of the radioactive waste may also include additional hazards, (e.g., biohazard or

chemical hazard). Such waste is called "mixed waste," and its storage and disposal must also comply with all other applicable Federal, state, and local regulatory requirements. Applicants should describe their program for management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, characterization, minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. Regulations require that licensees maintain all appropriate records of disposal of radioactive waste. The U.S. Environmental Protection Agency (EPA) issued guidance for developing a comprehensive program to reduce hazardous waste that, in many instances, may also include radioactive waste. NRC transmitted these guidelines to licensees in IN-94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program," dated March 1994.

Disposal By Decay-in-storage (DIS)

NRC has concluded that materials with half-lives of less than or equal to 120 days are appropriate for DIS. The minimum holding period for decay is ten half-lives of the longest-lived radioisotope in the waste. Such waste may be disposed of as ordinary trash if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that radiation levels are indistinguishable from background. All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed.

Applicants should assure that adequate space and facilities are available for the storage of such waste. Licensees can minimize the need for storage space, if the waste is segregated according to physical half-life. Waste containing radioisotopes of physical half-lives within a certain range may be stored in one container and allowed to decay for at least ten half-lives of the longest-lived radioisotope in the container. Procedures for management of such waste should include methods of segregation, surveys prior to disposal, and maintenance of records of disposal. Records should include the date when the waste was put in storage for decay, date when ten half-lives of the longest-lived radioisotope have transpired, date of disposal, and results of final survey before disposal as ordinary trash. Additionally, a model procedure for disposal of radioactive waste by DIS, which incorporates the above guidelines, is provided in Appendix T.

Release Into Sanitary Sewerage

10 CFR 20.2003 authorizes disposal of radioactive waste by release into a public sanitary sewerage system if each of the following conditions is met:

- Material is readily soluble (or is easily dispersible biological material) in water
- Quantity of licensed material that the licensee releases into the sewer each month averaged over the monthly volume of water released into the sewer does not exceed the concentration specified in 10 CFR Part 20, Appendix B, Table 3

- If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3 cannot exceed unity

- Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3, 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci) of all other radioisotopes combined.

Licensees are responsible to demonstrate that licensed materials discharged into the public sewerage system are indeed readily soluble in water. NRC IN 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20," dated January 1994, provides acceptable criteria for evaluating solubility of liquid waste. Liquid scintillation media and ash are examples of material that may or may not be "readily dispersible." Careful consideration should be given to the possibility of reconcentration of radioisotopes that are released into the sewer. NRC alerted licensees to the potentially significant problem of reconcentration of radionuclides released to sanitary sewerage systems in IN 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)," dated December 1984.
The regulations in 10 CFR 20.2003 are not applicable for releases to a private sewerage treatment system, a septic system, or leach fields. Licensees may make releases to these systems as effluents released to unrestricted areas pursuant to 10 CFR 20.1301. However, if licensed material is released to a private sewage treatment system, septic system, or leach field, the sludge or other solids from these systems may become contaminated with radioactive material. Such sludges may be required to be disposed of as radioactive waste, using one of the methods described in Section 8.11 of this document.
Applicants should provide procedures that will ensure that all releases of radioactive waste into the sanitary sewerage meet the criteria stated in 10 CFR 20.2003 and do not exceed the monthly and annual limits specified in regulations. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage. A model program for disposal of radioactive waste via sanitary sewer is described in Appendix T.

Transfer to an Authorized Recipient

Licensees may transfer radioactive waste to an authorized recipient for disposal. It is the licensee's responsibility to verify that the intended recipient is authorized to receive the radioactive waste prior to making any shipment. Almost all radioactive waste generated at ARDL facilities consists of low specific activity (LSA) material. The waste must be packaged in approved containers for shipment, and each container must identify the radioisotopes and the amounts contained in the waste. Additionally, packages must comply with the requirements of the particular burial site's license and state requirements. Each shipment must comply with all applicable NRC and DOT requirements. In some cases, the waste handling contractor may provide guidance to the licensee for packaging and transportation requirements; however, the licensee is ultimately responsible for ensuring compliance with all applicable regulatory requirements.

The shipper must provide all information required in NRC s Uniform Low-Level Radioactive Waste Manifest, and transfer this recorded manifest information to the intended recipient in accordance with 10 CFR Part 20, Appendix G. Each shipment manifest must include a certification by the waste generator, as specified in Section II of the appendix. Each person involved in the transfer for disposal and disposal of waste, including waste generator, waste collector, waste processor, and disposal facility operator, must comply with requirements specified in Section III of Appendix G.

Licensees should implement procedures to reduce the volume of radioactive waste for final disposal in an authorized low-level radioactive waste (LLW) disposal facility. These procedures include volume reduction by segregating, consolidating, compacting, or allowing certain waste to decay in storage. Waste compaction or other treatments can reduce the volume of radioactive waste, but such processes may pose additional radiological hazards (e.g., airborne radioactivity) to workers and members of the public. The program should include adequate safety procedures to protect workers, members of the public, and the environment.

Disposal of Specific Waste As If It Were Not Radioactive

The following radioactive wastes may be disposed of as non-radioactive waste:

- Liquid scintillation media (including vials and other items contaminated with liquid scintillation media) containing no more than 1.85 kBq (0.05 Ci) of H-3 or C-14 per gram of the medium; and

- Animal carcasses or animal tissue containing no more than 1.85 kBq (0.05 Ci) of H-3 or C-14 per gram averaged over the weight of the entire animal.

Applicants should have procedures that will ensure that the above limits are not exceeded and that the disposal of animal tissue or carcasses containing licensed material is in a manner that will not permit their use either as food for humans or animals. Applicants must maintain accurate records of these disposals.

Alternate Methods

Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste, and the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information on the nature of the environment, nature and location of other affected facilities, and procedures to ensure that radiation doses are maintained ALARA and within regulatory limits.

Some licensees do not have an LLW disposal facility available to them and therefore must use on-site interim storage until such time that a facility becomes available. Licensees should exhaust all possible alternatives for disposal of radioactive waste and rely upon on-site extended interim storage of radioactive waste only as a last resort. The protection of workers and the public is enhanced by disposal rather than storage of waste.

Licensees may also find it more economical to dispose of radioactive waste than to store it on-site because as the available capacity decreases, the cost of disposal of radioactive waste may continue to increase. Other than DIS, LLW should be stored only when disposal capacity is unavailable and for no longer than is necessary. NRC IN 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW.

Response from Applicant:

Provide a statement that: "We will use the model waste procedures published in Appendix T to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999."

OR

If the applicant wishes to use only selected model procedures, provide a statement that "We will use the (specify either (1) Decay-In-Storage, or (2) Disposal of Liquids Into Sanitary Sewerage) model waste procedures that are published in Appendix T to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999."

OR

Provide procedures for waste collection, storage and disposal by any of the authorized methods described in this section. Applicants should contact appropriate Regional Office of the NRC for guidance to obtain approval of any method(s) of waste disposal other than those discussed in this section.

OR

If access to a radioactive waste burial site is unavailable, the applicant should request authorization for extended interim storage of waste. Applicant should refer to NRC IN 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990, for guidance and submit the required information with the application.

Note: Applicants do not need to provide information to NRC if they plan to dispose of LLW via transfer to an authorized recipient or to dispose of liquid scintillation media or animals containing low levels of H-3 or C-14 as authorized by 10 CFR 20.2005. Alternative responses will be reviewed using the criteria listed above.

References: See the Notice of Availability on the inside front cover of this report to obtain copies of:

- Information Notice 94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program," dated March 1994
- Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20," dated January 1994
- Information Notice 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)," dated December 1984
- Information Notice 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990

Information Notices are available at <http://www.nrc.gov>.

Additional References:

- Policy and Guidance Directive PG 8-10, "Disposal of Incinerator Ash as Ordinary Waste," dated January 1997
- Policy and Guidance Directive PG 94-05, "Updated Guidance on Decay-In-Storage," dated October 1994
